

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re The Application Of	:	
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Nicholas V. Perricone	:	Examiner: Simon J. Oh
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Serial No.: 10/625,244	:	Group Art Unit: 1618
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Filed: June 30, 2003	:	
	:	
For: Topical Benfotiamine Treatments :	:	

Reply Brief Under 37 CFR §41.41

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Appellant submits its Reply Brief to the Examiner's Answer dated January 29, 2007.

The Examiner's argument asserts that any prior art disclosure of a topical composition having a main active ingredient, which further discloses myriad possible adjunct ingredients, will render unpatentable any subsequent invention for a method of topical prevention or topical treatment using one of those possible adjunct ingredients, if a different reference discloses topical use of the adjunct ingredient for another purpose. The Examiner asserts that in such a situation, it would be obvious to combine the references.

In particular, the Examiner asserts that Runge, U.S. Patent 6,261,598 "reads on" the claim language of the present application because it recites benfotiamine as a possible ingredient in the Runge composition, and Woerwag discloses benfotiamine compositions useful for treating rheumatic disorders and shingles, so that a person of ordinary skill in the art would conclude that benfotiamine could be used to (a) treat aging (b) prevent glycation; and (c) treat glycation, as specified by the claims.

This unsupported assumption is reversible error. See, e.g., *Ex parte Yamamoto*, 57 USPQ2d 1382 (BPAI 2000) (unpublished opinion):

the examiner has not established by evidence or explanation that long-chain unsaturated aliphatic ester, alcohol, ketone or hydrocarbons are stabilized by the combination of stabilizers utilized by Ishihara of record, or that one of ordinary skill in the art would have had a reasonable expectation that Ishihara's composition would be suitable for that use. The examiner has merely conjectured and speculated that because Ishihara's composition is directed to stabilized higher aliphatic aldehyde compounds it would be considered by one of ordinary skill in the art to be suitable for the stabilization of the claimed functional group containing compounds, and such speculation is not sufficient for establishing a prima facie case of obviousness. It is well settled that a rejection based on §103 must rest upon a factual basis rather than conjecture, or speculation. "Where the legal conclusion [of obviousness] is not supported by the facts it cannot stand." *In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967); see also *In re Sporck*, 301 F.2d 686, 690, 133 USPQ 360, 364 (CCPA 1962).

See also, *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994);

Runge, U.S. Patent 6,261,598, discloses carotenoid formulations comprising a mixture of β -carotene, lycopene and lutein. The composition of Runge is primarily intended as a food colorant (See Col. 3, line 61-Col. 4, line 1) and as a food supplement (Col. 4, lines 21-33). The composition is also indicated to be useable in topical products but the purpose of the use is not explained. Based on the disclosure of

the patent, the purpose of the use of the Runge composition in topical products appears to be use as a coloring agent.

Benfotiamine is mentioned among a plethora of other possible ingredients which could be added to make up the Runge composition. There is no discussion in Runge of the properties or effects of benfotiamine, or of the use of benfotiamine in a topical composition to improve skin condition. As noted in the Examiner's Answer, Runge does not teach methods of treating skin damage. (Answer, at p. 3).

Woerwag '087 discloses topical uses of benfotiamine for the treatment of pain associated with rheumatism, joint and neurological problems. Woerwag clearly states that the formulations of his invention are to be applied to the skin in order to reach areas below the skin, in order to increase the concentration of active component in those areas. See Evidence Appendix, Woerwag Translation at col. 1, lines 52-57. The use of benfotiamine to treat pain associated with an inflamed foot joint is used as an example. See Evidence Appendix, Woerwag Translation at col. 1, lines 31-47; see also col. 2, lines 13-45) (pain treatment).

As in *Ex parte Yamamoto*, the Examiner has merely speculated that because benfotiamine is used in a topical composition for treatment of neurological pain and other neurological disorders, that it would be obvious to use benfotiamine to (a) treat aging (b) prevent glycation; and (c) treat glycation, as specified by the claims of the application. This is error, and the rejection should be reversed.

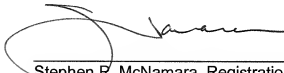
As previously noted in the Appeal Brief, Woerwag merely discloses delivery through-the-skin only in order to reach internal body parts for action upon the affected

cells thereof, delivering benfotiamine therapy internally, and in alternate delivery form to the well-known oral therapies. In contrast, all claims of the present invention requires compositions acting directly upon the cells of skin to (a) treat aging (b) prevent glycation; and (c) treat glycation. Runge and Woerwag do not teach or suggest benfotiamine for improvement of skin, wherein the composition reduces the quantity of glycated proteins or reduces the formation of glycated proteins as is presently claimed.

The claimed invention would not have been obvious to a person of ordinary skill in the art at the time of the invention thereof. Accordingly, for all of the foregoing reasons, the rejection of claims 1-18 and 21-26 should be reversed, and it is respectfully requested that the Examiner be directed to issue a Notice of Allowance of claims 1-18 and 21-26.

Respectfully submitted,

March 28, 2007



Stephen P. McNamara, Registration No. 32,745
ST. ONGE STEWARD JOHNSTON & REENS LLC
986 Bedford Street
Stamford, Connecticut 06905
(203) 324-6155

Attorneys for Appellant